HB290 HD1

Measure Title: RELATING TO THE UNIFORM CONTROLLED

SUBSTANCES ACT.

Report Title: Uniform Controlled Substances Act

Updates the Uniform Controlled Substances Act to

make it consistent with amendments in federal

Description: controlled substances law as required under the

authority to schedule controlled substances. (HB290

HD1)

Companion:

Package: None

Current Referral:

CPH, JDC

Introducer(s): SAN BUENAVENTURA, BROWER, C. LEE, MIZUNO,

MORIKAWA, THIELEN



STATE OF HAWAII DEPARTMENT OF PUBLIC SAFETY

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TESTIMONY ON HOUSE BILL 290, HOUSE DRAFT 1 RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

by Nolan P. Espinda, Director Department of Public Safety

Senate Committee on Commerce, Consumer Protection, and Health Senator Rosalyn H. Baker, Chair Senator Stanley Chang, Vice Chair

Friday, March 15, 2019; 9:00 a.m. State Capitol, Conference Room 229

Chair Baker, Vice Chair Chang, and Members of the Committee:

The Department of Public Safety (PSD) supports House Bill (HB) 290, House Draft (HD) 1 and offers comments. HB 290, HD 1 proposes to permanently authorize a new controlled substance, known by the brand name "Epidiolex", as a schedule V controlled substance, which will allow for public marketing in Hawaii. This measure, however, includes an additional amendment that creates an exception for Epidiolex in schedule I of chapter 329, HRS that may cause confusion and have unintended consequences.

Epidiolex has been added to schedule V of the federal drug schedules. PSD supports Section 2 of this measure which adds Epidiolex to schedule V of chapter 329, HRS, to mirror the recent change to the federal Controlled Substances Act for Epidiolex, eliminating differences between federal and state law.

There is, however, no exception for Epidiolex in schedule I of the federal drug schedules. As such, PSD would recommend that Section 1 of HB 290, HD 1 be deleted in its entirety, as it is inconsistent with federal law.

Thank you for the opportunity to testify on this measure.

POLICE DEPARTMENT

CITY AND COUNTY OF HONOLULU

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OUR REFERENCE CT-TA

March 15, 2019

The Honorable Rosalyn H. Baker, Chair and Members Committee on Commerce, Consumer Protection, and Health State Senate Hawaii State Capitol 415 South Beretania Street, Room 229 Honolulu, Hawaii 96813

Dear Chair Baker and Members:

SUBJECT: House Bill No. 290, H.D. 1, Relating to the Uniform Controlled Substances Act

I am Major Calvin Tong of the Narcotics/Vice Division of the Honolulu Police Department (HPD), City and County of Honolulu.

The HPD supports House Bill No. 290, H.D. 1, Relating to the Uniform Controlled Substances Act.

This bill seeks to update the Uniform Controlled Substances Act to make it consistent with the amendments in the federal controlled substance law as required under the authority to scheduled controlled substances.

It indicates that the controlled substance, "Approved cannabidiol drugs," falls under Schedule V and are an exception under Tetrahydrocannabinols in Schedule I. These approved cannabidiol drugs are approved by the United States Food and Drug Administration.

The HPD asks you to support House Bill No. 290, H.D.1, Relating to the Uniform Controlled Substances Act.

Thank you for the opportunity to testify.

APPROVED:

gusan Ballard

Chief of Police

Sincerely,

Calvin Tong, Major

Narcotics/Vice Division

Serving and Protecting With Aloha



Akamai Cannabis Clinic

3615 Harding Ave, Suite 304 Honolulu, HI 96816

TESTIMONY ON HOUSE BILL 290 HOUSE DRAFT 1 RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT By Clifton Otto, MD

Senate Committee on Commerce, Consumer Protection, and Health Senator Rosalyn H. Baker, Chair Senator Stanley Chang, Vice Chair

> Friday, March 15, 2019; 9:00 AM State Capitol, Conference Room 229

Thank you for the opportunity to provide testimony on this measure. Please consider the following comments related to this bill:

Comment #1 - A controlled substance that has been accepted for medical use in Hawaii cannot have the highest degree of danger under our state Uniform Controlled Substances Act (UCSA).

The solution to this situation rests with the phrase "does not apply", for which we have several notable examples:

Exempt from federal Schedule I:

21 CFR 1307.31 - Native American Church.

The listing of peyote as a controlled substance in Schedule I <u>does not apply</u> to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration.

Exempt from Guam Schedule I:

Section 2. The following *new* subsection (g) is added to Appendix A of Chapter 67 of Title 9 Guam Code Annotated, to read as follows:

"(g) The enumeration of marihuana, tetrahydrocannabinols or chemical derivatives of these as Schedule I controlled substances **does not apply** to the medical use of cannabis pursuant to the Joaquin Concepcion Compassionate Cannabis Use Act of 2013."

Exempt from federal restriction on carriage aboard aircraft:

14 CFR 91.19 Carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances.

- (a) Except as provided in paragraph (b) of this section, no person may operate a civil aircraft within the United States with knowledge that narcotic drugs, marihuana, and depressant or stimulant drugs or substances as defined in Federal or State statutes are carried in the aircraft.
- (b) Paragraph (a) of this section <u>does not apply</u> to any carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances authorized by or under any Federal or State statute or by any Federal or State agency.

Therefore, the following amendment needs to be made in order to harmonize the accepted medical use of cannabis in Hawaii with our state scheduling regulations:

Section 329-14, Hawaii Revised Statutes, is amended by adding the following subsection:

(f) The enumeration of cannabis, tetrahydrocannabinols or chemical derivatives of these as Schedule I controlled substances does not apply to the medical use of cannabis pursuant to Section 329, Part IX, and Section 329D, Hawaii Revised Statutes.

Failure to recognize this exemption will only continue to hamper effective enforcement of state and federal cannabis regulation. Recognizing this exemption will allow our dispensaries to finally operate as legitimate businesses.

Comment #2 - If the reason for annually updating Hawaii's Uniform Controlled Substances Act is to harmonize the state and federal regulation of controlled substances, then the Drug Enforcement Administration (DEA) Marijuana Extract rule needs to be considered:

https://www.federalregister.gov/documents/2016/12/14/2016-29941/establishment-of-a-new-drug-code-for-marihuana-extract

21 CFR 1308.11(d) (58) Marihuana Extract - 7350

"Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant."

https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html

Comment #3 – Along similar lines, if FDA-approved Cannabidiol (CBD) needs to be placed into a state controlled substance schedule that is similar to the federal schedule adopted by the DEA, then what does this tell us about the current state scheduling of non-FDA-approved CBD?

Hawaii is being inundated with imported and locally formulated CBD products without any regulation to insure consumer safety or compliance with state and federal controlled substance regulation. Before allowing this bill to pass through your committee, please address the scheduling status of non-FDA-approved CBD by answering the following question:

Is CBD a tetrahydrocannabinol or a derivative of a tetrahydrocannabinol?

HRS 329-14. Schedule I. (a) The controlled substances listed in this section are included in Schedule I.

- (g) Any of the following cannabinoids, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:
- (1) Tetrahydrocannabinols; meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, **derivatives**, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following: Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; and Delta 3,4 cis or trans tetrahydrocannabinol, and its optical isomers (since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions, are covered):

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6154432/pdf/can.2018.0030.pdf Delta-8-THC (Delta-6-THC):

https://pubchem.ncbi.nlm.nih.gov/compound/2977#section=Top Delta-9 THC (Delta-1-THC):

https://pubchem.ncbi.nlm.nih.gov/compound/Dronabinol#section=Top

This question is of critical importance now that a CBD oil made in England (Epidiolex) is an FDA-approved drug product in the United States.

The <u>Food and Drug Administration</u> (FDA) is very clear about the status of CBD and THC as food additives or dietary supplements:

"Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug."

Failure to address the scheduling status of non-FDA-approved CBD products will only allow the unregulated importation of untested and potentially dangerous CBD snake oils to continue, until the FDA or the Department of Justice will have to step in and bring into question the ability of the State to properly regulate its own Hemp and Medical Use of Cannabis Programs.

Comment #4 – The inter-island transportation of cannabis for personal medical use continues to be an issue that is requiring significant amounts of local law enforcement time due to the processing of patients at our state airports who have been referred by TSA, which is distracting our officers from more important law enforcement duties and threatening the safety of our airports.

Local law enforcement officers are also telling patients that they cannot travel with their medicine because it is against federal law, which is beyond the enforcement authority of a state law enforcement agency.

All of this despite our Medical Use of Cannabis Act, which only prohibits patients from transporting to other islands for the purpose of transferring to another patient, and a long-time federal aviation regulation, which specifically exempts the carriage of marijuana aboard aircraft if authorized by state law or state agency:

14 CFR 91.19 Carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances.

- (a) Except as provided in paragraph (b) of this section, no person may operate a civil aircraft within the United States with knowledge that narcotic drugs, marihuana, and depressant or stimulant drugs or substances as defined in Federal or State statutes are carried in the aircraft.
- (b) Paragraph (a) of this section **does not apply** to any carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances **authorized by** or under any Federal or **State statute** or by any Federal or **State agency**.

Therefore, in order to clarify the existing provisions for inter-island transport within Hawaii's Medical Use of Cannabis Act, and to protect the right of patients to transport legal amounts of cannabis for personal medical use to other islands under state law and the Americans with Disabilities Act, the following amendment needs to be made to the Medical Use of Cannabis section of Hawaii's Uniform Controlled Substances Act:

HRS 329-122(f):

"For purposes of interisland transportation, "transport" of cannabis, usable cannabis, or any manufactured cannabis product, by any means is allowable only by a qualifying patient or qualifying out-of-state patient for their personal medical use, or between a production center or retail dispensing location and a certified laboratory for the sole purpose of laboratory testing pursuant to section 329D-8, as permitted under section 329D-6(m) and subject to section 329D-6(j), and with the understanding that state law and its protections do not apply outside of the jurisdictional limits of the State. The Department of Transportation and the Department of Public Safety shall adopt rules to provide compliance with this section.

TESTIMONY OF NAHELANI WEBSTER ON BEHALF OF GREENWICH BIOSCIENCES IN SUPPORT OF H.B. 290 HD1

To: Chair Rosalyn H. Baker and Members of the Senate Committee on Commerce, Consumer Protection, and Health

My name is Nahelani Webster and I am presenting this testimony on behalf of Greenwich Biosciences (GW) in **support** of H.B. 290 HD1 Relating to the Uniform Controlled Substances **with a requested amendment**.

The purpose of this bill is to update our state statute to make it consistent with amendments in the federal controlled substances law as required under Hawaii Revised Statutes ("HRS") section 329-11. This will allow for Epidiolex to continue to be available to the public in the State of Hawaii.

This measure would add very specific language to HRS § 329-22, which is an extremely narrow formula, only applicable to Epidiolex. **This does** <u>not</u> impact nor apply to any other forms of cannabidiol products. The specific formula also requires FDA approval.

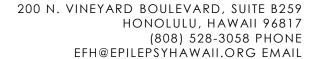
Epidiolex was approved by the U.S. Food and Drug Administration (FDA) on June 25, 2018 for the treatment of seizures associated with Lennox Gastaut syndrome (LGS) and Dravet syndrome, two rare and difficult-to-treat forms of childhood-onset epilepsy, in patients two years of age or older. Epidiolex is a Schedule V drug, the lowest DEA restriction classification, based on its low abuse potential.

By adding Epidiolex to current treatment, seizures were significantly reduced in those with Dravet and LGS who were not previously helped with various epilepsy medicines. The company is always seeking solutions that will transform lives, and this is why GW continues to advance cannabinoid science and study new medications to help meet serious unmet patient and caregiver needs.

This committee previously heard SB1263 Relating to Uniform Controlled Substances. We strongly support the language in the SD1 and respectfully ask the committee to make similar amendments to this measure.

For GW, Epidiolex is just the first step toward transforming the treatment of epilepsy in one's lifetime.

Thank you for the opportunity to present this testimony. Please contact me if you have any questions.





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EXECUTIVE DIRECTOR

Naomi Manuel

March 13, 2019

Aloha Chair Baker and Members of the Committee on Commerce, Consumer Protection, and Health.

I am writing in support of H.B. 290 Relating to the Uniform Controlled Substances Act along with a proposed amendment to add in language necessary to reschedule the currently FDA approved Epidiolex formula to Schedule V, in conformity with federal law. The purpose of the language is to update our state statute to make it consistent with amendments in the federal controlled substances law as required under Hawaii Revised Statutes ("HRS") section 329-11. This will allow for Epidiolex to be available to the public in the State of Hawaii.

Epidiolex was approved by the U.S. Food and Drug Administration (FDA) on June 25, 2018 for the treatment of seizures associated with Lennox Gastaux syndrome (LGS) and Dravet syndrome, two rare and difficult-to-treat forms of childhood-onset epilepsy, in patients two years of age or older. As of October 29, 2018, Epidiolex has been made available to patients in Hawaii under the Department of Public Safety's temporary rescheduling action.

Epidiolex is a Schedule V drug, the lowest DEA restriction classification, based on its low abuse potential. By adding Epidiolex to current treatment, seizures are significantly reduced in those with Dravet and LGS who were not previously helped with various epilepsy medicines. Unless Hawaii acts now individuals with Dravet and Lennox-Gastaut syndromes could experience a delay in accessing this new and innovative treatment option, a reduction in seizures, and an improved quality of life.

The Epilepsy Foundation of Hawaii is an affiliate of the Epilepsy Foundation of America and together we are the leading national voluntary health organization that speaks on behalf of the at least 14,000 individuals in Hawaii (3.4 million Americans) and their caregivers living with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services.

Mahalo for the opportunity to present this testimony. Please contact me if you have any questions.

Naomi Manuel

Executive Director

Noon Manuel

The mission of the Epilepsy Foundation of Hawaii is to lead the fight to overcome the challenges of living with epilepsy and to accelerate therapies to stop seizures, find cures, and save lives. The Epilepsy Foundation of Hawaii is an affiliate of the Epilepsy Foundation of America. It is an independent 501(c)(3) Hawaii non-profit organization. Federal ID: 23-7216782.

From: John Calvert < jcalvert@crystal3.com>

Subject: Support for HB290 with amendments

Aloha Members of the Committee

Please be aware that CBD as a "drug" is not the same as CBD oil derived from natural extraction of cannabinoids from hemp flowers, as would be done by farmers in Hawaii. The latter is called "full spectrum" CBD oil, and it has been found to have higher therapeutic value than purified CBD isolate (i.e. drug-form or pharmaceutical CBD).

While it is appropriate to include language to regulate "drug-type" cannabidiol as a Schedule V substance, I strongly recommend that cannabidiol derived from legally-grown hemp to be exempt from the Controlled Substances list. The language in HB290 should be modified to specifically exclude "THC from hemp" from Section 329–14, Hawaii Revised Statutes... "(1) Tetrahydrocannabinols... provided that tetrahydro-cannabinols under this subsection shall exclude tetrahydrocannabinols in hemp;"

Regarding Section 329–22, Schedule V, I strongly suggest adding language that specifically excludes hemp extracts containing cannabidiol from the definition of "Approved cannabidiol drugs." Cannabidiol derived from hemp through natural extraction methods is a key process for Hawaii's farmers who wish to grow CBD hemp and produce CBD oil.

Thank you for your consideration,

Mahalo,

John Calvert

small farmer, lower Puna district, Big Island